

In the United States Court of Federal Claims

No. 10-197V

Filed: September 29, 2016

H.L., on Behalf of A.I., Deceased,

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Petitioner,

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v.

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Causation-in-fact (Significant Aggravation);

FluMist Vaccine;

Leigh Disease;

42 U.S.C. §§ 300aa-1–34 (Vaccine Act).

SECRETARY OF HEALTH AND
HUMAN SERVICES,

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Respondent.

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Robert Krakow, Law Office of Robert J. Krakow, P.C. New York, New York, Counsel for Petitioner.

Justine Elizabeth Walters, United States Department of Justice, Civil Division, Washington, D.C., Counsel for Respondent.

MEMORANDUM OPINION AND FINAL ORDER

BRADEN, *Judge*.

Petitioner requests review of the Special Master's March 17, 2016 Decision, denying an award under the Vaccine Act.¹

¹ The applicable statutory provisions of the Vaccine Act are codified at 42 U.S.C. §§ 300aa-1–34 (2012).

I. RELEVANT FACTUAL BACKGROUND.²

On January 11, 2008, six-year-old “A.I.” received the FluMist vaccine. 3/17/16 Dec. at 6.³ That evening, A.I. began having “staring spells.” 3/17/16 Dec. at 7. On January 22, 2008, A.I. was taken to an urgent care facility, after suffering from a variety of symptoms, including: discomfort while urinating; sensitivity in her eyes; and periods of disorientation. 3/17/16 Dec. at 7. A.I. was discharged the same day with instructions to follow up with her pediatrician. 3/17/16 Dec. at 7. On January 28, 2008, A.I. was seen at her pediatrician’s office for a follow up examination. 3/17/16 Dec. at 8.

Subsequently, A.I. and her mother, H.L., had mitochondrial DNA testing. 3/17/16 Dec. at 8. The results indicated that A.I. and H.L. had genetic mutations commonly associated with NARP (Neuropathy,⁴ Ataxia,⁵ and Retinitis Pigmentosa⁶) and Leigh Disease.⁷ 3/17/16 Dec. at 8.

On March 15, 2008, A.I. was taken to the Children’s Hospital, because she experienced an episode of unconsciousness and difficulty breathing. 3/17/16 Dec. at 8. At the hospital, A.I. was diagnosed with possible hypoxic seizures⁸ and respiratory distress. 3/17/16 Dec. at 8. On that same day, A.I. was transported to Presbyterian/St. Luke’s Medical Center, where a sleep

² The relevant facts were derived from the Special Master’s March 17, 2016 Decision denying compensation. *See H.L. v. Sec’y of Health & Human Servs.*, No. 10-0197V (Fed. Cl. Spec. Mstr. Mar. 17, 2016), ECF No. 134 (“3/17/16 Dec.”).

³ FluMist Quadrivalent is a registered trademark of the AstraZeneca group. *See* Important Safety and Eligibility Information, FLUMIST QUADRIVALENT, <https://www.flumistquadrivalent.com/> (last visited Aug. 25, 2016).

⁴ Neuropathy is a “functional disturbance or pathological change in the peripheral nervous system, sometimes limited to noninflammatory lesions as opposed to those of neuritis; the etiology may be known or unknown.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1268 (32d ed. 2012) (“DORLAND’S”).

⁵ Ataxia is a “failure of muscular coordination; irregularity of muscular action.” DORLAND’S at 170.

⁶ Retinitis Pigmentosa is a “group of diseases, frequently hereditary, marked by progressive loss of retinal response (as elicited by the electroretinogram), retinal atrophy, attenuation of the retinal vessels, and clumping of the pigment, with contraction of the field of vision.” DORLAND’S at 1634.

⁷ Leigh Disease is a “subacute necrotizing encephalomyelopathy.” DORLAND’S at 1018. Encephalomyelopathy is “any disease involving the brain and muscles.” *Id.* at 614.

⁸ Hypoxia is a “reduction of oxygen supply to tissue below physiological levels despite adequate perfusion of the tissue by blood.” DORLAND’S at 908.

study evidenced that A.I. suffered from a seizure and severe sleep-disordered breathing, which was caused by prolonged disruptive hypoventilation, snoring and labored breathing associated with hypoxemia. 3/17/16 Dec. at 8.

On April 5, 2008, A.I. died. 3/17/16 Dec. at 9. The cause of death was cited as “Leigh Syndrome.” 3/17/16 Dec. at 9. No autopsy was performed. 3/17/16 Dec. at 9.

II. PROCEDURAL HISTORY.

On April 1, 2010, H.L. (“Petitioner”) filed a Petition under the National Vaccine Injury Compensation Program, on behalf of her deceased daughter, A.I. (“Pet.”). The Petition alleged that, on January 11, 2008, A.I. was administered an influenza vaccine, FluMist, that “significantly aggravated [A.I.’s] metabolic and mitochondrial disorder, leading to serious complicating medical problems and causing her death on April 5, 2008.” Pet. at 2. Petitioner also filed medical records and other records marked as Petitioner’s Exhibits (“Pet. Exs. 1–22”). The case was assigned to Special Master Gary Golkiewicz.

On June 30, 2010, the Government filed a Vaccine Rule 4 Report, contending that Petitioner failed to meet the burden of proving causation or significant aggravation. Rule 4 Report, ECF No. 8, at 10. The Government did not dispute that A.I. suffered from Leigh Disease or that her death was caused by this disease, however, the Government contends that the facts of this case do not establish that A.I.’s Leigh Disease was caused or aggravated by the FluMist vaccine, because no causal connection was identified by A.I.’s treating physicians. Rule 4 Report, ECF No. 8, at 10.

On July 12, 2010, the Special Master issued a Scheduling Order and convened a telephone status conference.

On September 1, 2010, Petitioner filed a Status Report, stating that Petitioner was “in active consultation with a pediatric neurologist [to retain] his services as an expert witness in this case.” ECF No. 10, at 1.

On October 12, 2010, Petitioner filed a Motion For Extension Of Time to file an expert report. On October 14, 2010, the Special Master granted Petitioner’s October 12, 2010 Motion, requiring Petitioner to file an expert report no later than January 11, 2011.

On December 2, 2010, the Special Master issued an Order, informing Petitioner that “[t]he statutory 240-day time period for . . . issuance of a decision in this case has expired.” ECF No. 13, at 1. Accordingly, the Special Master advised Petitioner to “submit to the United States Court of Federal Claims a notice in writing [electing either] to continue or to withdraw the petition” within 30 days. ECF No. 13, at 1.

On January 12, 2011, Petitioner filed a Status Report, advising the Special Master that Petitioner would “be filing a [M]otion seeking an Order for the payment of interim fees for expert services[.]” ECF No. 14, at 1. On January 25, 2011, the Special Master convened a status conference that was not officially recorded. On January 26, 2011, the Special Master issued another Scheduling Order, requiring Petitioner to file a Status Report about efforts to obtain an expert report. On April 28, 2011, the Special Master issued an Order Regarding Petitioner’s

Noncompliance, requiring Petitioner to file a Status Report by no later than May 12, 2011. ECF No. 17, at 1. On May 11, 2011, Petitioner filed a Status Report, stating that the expert witness who previously agreed to serve was no longer available so that “additional time [was needed] to identify an expert witness[.]” ECF No. 18, at 1–2. On August 17, 2011, the Special Master issued an Order, requiring Petitioner to file a Status Report about the renewed efforts to obtain an expert by August 31, 2011. On August 31, 2011, Petitioner filed a Status Report, advising the Special Master that a replacement expert witness was retained. On September 1, 2011, the Special Master issued an Order, requiring Petitioner to file an expert report by no later than November 30, 2011. On November 29, 2011, Petitioner filed an Unopposed Motion For Extension Of Time until January 23, 2012 to file the expert report that the Special Master granted.

On January 23, 2012, Petitioner filed an Expert Report by Dr. Frances D. Kendall. On January 26, 2012, the case was reassigned to then-Chief Special Master Patricia Campbell-Smith. On July 17, 2012, Respondent filed an Expert Report by Dr. Shawn E. McCandless.

On May 28, 2013, the case was reassigned to Special Master George L. Hastings, Jr. and an evidentiary hearing was scheduled for July 26, 2013. On July 3, 2013, both parties filed pre-hearing submissions and a supplemental declaration was filed by Petitioner. On July 26, 2013, the Special Master convened an evidentiary hearing (“7/26/13 TR 1–229”) and heard testimony, including from the parties’ experts, Dr. Kendall and Dr. McCandless.

On December 14, 2014, Petitioner filed a Post-Hearing Brief. On April 22, 2015, the Government filed a Response. On June 9, 2015, Petitioner filed a Reply. On August 3, 2015, the Government filed an additional Supplemental Brief. On September 3, 2015, Petitioner filed a Response to address the relevance of the United States Court of Appeals for the Federal Circuit’s decision in *Paluck v. Dep’t of Health & Human Servs.*, 786 F.3d 1373 (Fed. Cir. 2015) (holding that the petitioners demonstrated by a preponderance of evidence that the vaccine aggravated the petitioners’ son’s preexisting mitochondrial disorder).

On March 17, 2016, the Special Master issued an Unpublished Decision Denying Compensation, finding that Petitioner did not meet her burden to establish that the FluMist vaccine caused the triggering of A.I.’s Leigh Disease or subsequent death. 3/17/16 Dec. at 12–31. Therein, the Special Master emphasized that neither A.I.’s medical records nor Dr. Kendall’s expert opinion supported a causal connection between the vaccine and injury. 3/17/16 Dec. at 12–31. Accordingly, the Special Master denied Petitioner’s claim. 3/17/16 Dec. at 12–31.

On April 18, 2016, Petitioner filed a Motion For Review with the United States Court of Federal Claims, and a Memorandum In Support Of Motion For Review (“Pet. Mem.”).

On May 18, 2016, the Government filed a Memorandum In Response To Petitioner’s Motion For Review (“Gov’t Mem.”).

On May 31, 2016, the Government filed a Notice Of Precedential Authority, discussing the United States Court of Appeals for the Federal Circuit’s recent precedential opinion, *Milik v. Sec’y of Health & Human Servs.*, 822 F.3d 1367 (Fed. Cir. 2016) (holding that the

Special Master's decision was not arbitrary or capricious, because he "thoroughly reviewed" all of the relevant evidence, including expert testimonies and reports).

III. DISCUSSION.

A. Jurisdiction.

The United States Court of Federal Claims has jurisdiction to review the decision of a Special Master in a vaccine-related injury case, pursuant to 42 U.S.C. § 300aa-12(e)(2) and Vaccine Rule 23(a). After reviewing the Special Master's decision, the court may:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); *see also* Vaccine Rule 27 of Appendix B of the Rules of the United States Court of Federal Claims ("Vaccine Rules").

B. Standard Of Review.

Congress authorized the United States Court of Federal Claims with jurisdiction to review conclusions of law made by Special Masters under the Vaccine Act *de novo*, *i.e.*, under a "not in accordance with law" standard. *See* 42 U.S.C. § 300aa-12(e)(2)(B); *see also Hines v. Sec'y Dep't of Health & Human Servs.*, 940 F.2d 1518, 1527 (Fed. Cir. 1991) ("The 'not in accordance with the law' aspect of the standard of review is . . . involved . . . [where there is] dispute over statutory construction or other legal issues."); *Saunders v. Sec'y Dep't of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 2004) (quoting *Munn v. Sec'y Dep't of Health & Human Servs.*, 970 F.2d 863, 870, n.10 (Fed. Cir. 1992) ("Fact findings are reviewed by [the United States Court of Appeals for the Federal Circuit], as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.")).

Factual findings of a Special Master should be set aside only if they are found to be "arbitrary and capricious" or if the Special Master has abused his/her discretion in making these findings. *See* 42 U.S.C. § 300aa-12(e)(2)(B). But, the United States Court of Appeals for the Federal Circuit has stated that there is "no uniform definition of this standard," and instructed that the decision of a Special Master may be found to be "arbitrary and capricious," only if he/she:

relied on factors which Congress has not intended [the Special Master] to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence . . . or is so

implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Hines, 940 F.2d at 1527–28 (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983)). Discretionary rulings are reviewed under an “abuse of discretion standard.” *Munn*, 970 F.2d at 870 n.10.

C. The Elements And Burden Of Proof In Vaccine Act Cases.

The Vaccine Act provides that a petitioner may receive compensation and other relief, if injury can be established either by causation in law or causation-in-fact. Causation in law is established if one of the vaccines listed in the Vaccine Injury Table at 42 U.S.C. § 300aa-14(a) (“Vaccine Table”) was administered to a petitioner and the “first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths” of specific adverse medical conditions associated with the use of each vaccine occurred within a time period specified in the Vaccine Table. *See* 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a). And, the Vaccine Table is to be read and interpreted by reference to “Qualifications and aids to interpretation,” that define the key terms used therein. *Id.*

Congress also afforded a petitioner with an opportunity to receive relief under the Vaccine Act, even if the time period for the first symptom or manifestation of a specified injury is not listed in the Vaccine Table, *i.e.*, was an “off-Table” vaccine injury. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii), § 300aa-13. Under these circumstances, a petitioner must establish causation-in-fact, by offering sufficient facts to establish each element of a vaccine injury claim, and meet the burden of proof as to each element by a “preponderance of the evidence” standard. *See* 42 U.S.C. § 300aa-13. In sum, an off-Table petitioner must proffer evidence as to each element of the claim and sufficient evidence to persuade the Special Master or court by a preponderance thereof. *Id.*

In *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006), the United States Court of Appeals for the Federal Circuit re-affirmed the three-part test established in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, (Fed. Cir. 2005) (“*Althen*”), for determining causation-in-fact in off-Table vaccine injury cases. Therein, a petitioner is required to:

show by preponderant evidence that the vaccination brought about [the] injury by providing:

- (1) a medical theory causally connecting the vaccination and the injury;
- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278.

If a petitioner established causation-in-fact, then the burden of proof shifts to the Government to establish that a factor unrelated to the vaccine was the cause of a petitioner’s injury. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *see also Althen*, 418 F.3d at 1278 (“If [a petitioner]

satisfies this burden, [she/he] is entitled to recover [damages] unless [the Government] shows, by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.”) (internal quotation marks omitted).

D. The Special Master’s March 17, 2016 Decision In This Case.

In this case, the Special Master determined that Petitioner’s expert, Dr. Kendall submitted a written report that was not specific in identifying any particular “first symptom.”⁹ 3/17/16 Dec. at 13. At the evidentiary hearing, however, Dr. Kendall testified that the staring spells that occurred within hours of the January 11, 2008 FluMist vaccination were the first symptoms signifying that the FluMist vaccine, at least in part, caused A.I.’s subsequent metabolic decompensation.¹⁰ 3/17/16 Dec. at 13.¹¹ In addition, Dr. Kendall “offered no citation to any medical literature supporting her contention that a mitochondrial decompensation could occur within hours of a vaccination[.]” 3/17/16 Dec. at 13. For this reason, among others, the Special Master determined that the Government’s expert, Dr. McCandless, submitted a more persuasive reasoning, as he testified that, if A.I. experienced staring spells on the same day she was diagnosed with upper respiratory infection, decompensation was more likely due to A.I.’s pre-existing infection. 3/17/16 Dec. at 13. Dr. McCandless also cited Joseph L. Edmonds et al., *The Otolaryngological Manifestations of Mitochondrial Disease and the Risk of Neurodegeneration With Infection*, 128 ARCHIVES OTOLARYNGOL HEAD NECK SURGERY 355 (2002), ECF No. 57-1 (“EDMONDS”) to support his opinion that “there should typically be a period of several days between the time of an infectious insult and the onset of neurological consequences.” 3/17/16 Dec. at 14.

The Special Master also noted that A.I.’s medical records indicated that A.I. experienced coughing for two days with a fever of 102 degrees before she visited her pediatrician on January 11, 2008 and received the FluMist Vaccine. 3/17/16 Dec. at 14. “Thus, consistent with [EDMONDS], it appears that the onset of A.I.’s neurodegeneration occurred approximately two to three days following the onset of her [upper respiratory] *infection*.” 3/17/16 Dec. at 14 (emphasis in original). Accordingly, the Special Master determined that the onset of mitochondrial decompensation within hours of the vaccination would “likely be *too soon* to be related to the vaccination.” 3/17/16 Dec. at 14 (emphasis in original). Although the United States Court of Appeals for the Federal Circuit has “cautioned against relying on isolated small-

⁹ Dr. Frances Dougherty Kendall is a biochemical geneticist with over 29 years of experience in medicine. 7/26/13 TR at 43; *see also* ECF No. 51-1 (curriculum vitae of Frances Dougherty Kendall). Dr. Kendall specializes in mitochondrial disease management and diagnosis. *See* 7/26/13 TR at 43.

¹⁰ Decompensation is a “failure of compensation.” DORLAND’S at 475. Compensation is the “counterbalancing of any defect of structure or function.” *Id.* at 393.

¹¹ But, Dr. Kendall also testified that the first well-documented sign of decompensation was when A.I. collapsed on January 22, 2008—11 days after the FluMist vaccination. *See* 7/26/13 TR at 61–66.

scale studies as creating clear-cut periods of onset,” in this case the Special Master concluded that EDMONDS was the only evidence in the record addressing the timing of mitochondrial decompensation. 3/17/16 Dec. at 14 (citing *Paluck*, 786 F.3d at 1383–84). Moreover, the Special Master stated that, even if he “were to find that the January 22 collapse, occurring 11 days post-vaccination, was the first symptom . . . [he] would still have to reject the Petitioner’s causation claim, for all of the *other* reasons stated in this Decision.” 3/17/16 Dec. at 14 n.8, 15 (emphasis in original).

The Special Master also found Dr. Kendall’s reasoning that A.I.’s history of not experiencing a mitochondrial decompensation after prior illnesses or vaccinations, concluding that the FluMist vaccination was an additional stress factor triggering decompensation to be unpersuasive. 3/17/16 Dec. at 15. Although both parties’ experts agreed that “the significance of A.I.’s January 11 illness, or any of her prior illnesses is effectively unknowable,” the Special Master determined that A.I.’s history of tolerating prior illnesses mitigated against finding A.I.’s vaccine was a causative factor in Leigh Disease and death. 3/17/16 Dec. at 15–16.

Dr. Kendall also testified that FluMist’s marketing information reported that there had been “exacerbation of symptoms of mitochondrial encephalomyelopathy (Leigh Syndrome)” after receiving the vaccine. 3/17/16 Dec. at 16. But, Dr. McCandless countered that “as a general matter, the medical community as a whole largely agrees that vaccines should be routinely administered to individuals with metabolic disorders.” 3/17/16 Dec. at 17 (citing J.D. Kingsley et al., *Immunizations for Patients with Metabolic Disorders*, 118 PEDIATRICS 460–70 (2006)) Therefore, the Special Master found Dr. Kendall’s citation to and reliance on FluMist’s post-marketing information unpersuasive. 3/17/16 Dec. at 16.

In reaching this conclusion, the Special Master considered Dr. Kendall’s cites to Jon S. Poling et al., *Developmental Regression and Mitochondrial Dysfunction in a Child with Autism*, 21 J. CHILD NEUROLOGY 170 (2006), ECF No. 26-8 (“POLING”) and John Shoffner et al., *Fever Plus Mitochondrial Disease Could Be Risk Factors for Autistic Regression*, J. CHILD NEUROLOGY 3 (2009), ECF No. 26-9 (“SHOFFNER”) to support her theory that the FluMist vaccine materially contributed to A.I.’s decompensation. 3/17/16 Dec. at 19. But, Dr. McCandless responded that these two studies were distinguishable, because “it is undisputed that A.I. did *not* experience an autistic regression.” 3/17/16 Dec. at 19–20 (emphasis in original). Moreover, Dr. Kendall did not provide support that the regression in POLING was similar to A.I.’s decompensation. 3/17/16 Dec. at 20. In other words, “[e]stablishing a theory that a vaccine can cause injury “X” is not the same as proving that it can cause injury “Y,” absent some evidence showing that injuries X and Y share sufficient commonality.” 3/17/16 Dec. at 20 n.16. The Special Master also distinguished this case from *Paluck*, 786 F.3d 1373, wherein the United States Court of Appeals for the Federal Circuit relied on POLING. 3/17/16 Dec. at 21. In *Paluck*, the Government conceded the plausibility of the petitioner’s causation theory solely for purposes of appeal. 3/17/16 Dec. at 21. In this case, however, the Special Master established that “unlike the appellate posture presented in *Paluck*, [here, the Government] *clearly is* vigorously contesting Petitioner’s ‘general causation’ theory.” 3/17/16 Dec. at 21 (emphasis in original).

Dr. Kendall also cited Brady et al., *Immunization Recommendations for Children with Metabolic Disorders: More Data Would Help*, PEDIATRICS 810 (2006) (“BRADY”). 3/17/16 Dec. at 23. But, the Special Master observed that, as Dr. McCandless argued, BRADY only indicated

that “immunizations ‘may’ cause *fever or anorexia*, [that] in turn *may* have a metabolic impact.” 3/17/16 Dec. at 23 (emphasis added). In addition, Dr. Kendall admitted that she was not aware of “any reliable study attributing acute metabolic decompensation to a flu vaccine among patients with Leigh Disease.” 3/17/16 Dec. at 24.

Although Dr. Kendall also cited articles that show that the wild flu virus can cause mitochondrial death, resulting in clinical symptoms, these studies concerned a wild flu virus different from the strain contained in the FluMist vaccine. 3/17/16 at 26. Therefore, the Special Master concluded that these articles do not support Dr. Kendall’s opinion that “the FluMist vaccine *in particular* played any role in A.I.’s . . . decompensation.” 3/17/16 Dec. at 26 (emphasis in original).

In sum, the Special Master determined that Petitioner failed to satisfy the *Althen* test. 3/17/16 Dec. at 28–31. Under Prong 1 of *Althen*, “a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause a significant worsening of the *type* of preexisting condition of the vaccine.” 3/17/16 Dec. at 29 (emphasis in original). Petitioner, however, did not proffer a medical theory demonstrating that the viral strain in the FluMist vaccine could cause or exacerbate Leigh Disease. 3/17/16 Dec. at 30. Under Prong 2 of *Althen*, a petitioner must show that it is more probable than not that a vaccine caused the injury. 3/17/16 Dec. at 31. The Special Master concluded that the medical articles cited by the parties’ experts “better supported [the Government’s] theory of the case than Petitioner’s.” 3/17/16 Dec. at 31. The Special Master further determined that, because Petitioner failed Prongs 1 and 2, he “need not discuss . . . the third prong.” 3/17/16 Dec. at 31. In addition, the Special Master determined that “the timing of A.I.’s first symptom of neurodegeneration (*i.e.*, the staring spells) . . . made the vaccination an unlikely explanation for A.I.’s . . . decompensation.” 3/17/16 Dec. at 31. Therefore, the Special Master concluded that “Petitioner failed to establish a proximate temporal relationship between the vaccination and A.I.’s . . . decompensation.” 3/17/16 Dec. at 31.

E. Petitioner’s April 18, 2016 Motion For Review.

1. Petitioner’s Memorandum In Support Of Motion For Review.

First, Petitioner argued that the Vaccine Act’s standard of review is unconstitutional, because “[b]y limiting a vaccine injury claimant to . . . an Article I court[,] the Vaccine Act has deprived petitioners of the rights granted in Article III of the United States Constitution and the common law protections afforded in state courts for tortious injuries against the manufacturers of vaccines.” Pet. Mem. at 21 (citing *Stern v. Marshall*, 131 S. Ct. 2594, 2609 (2011) (“When a suit is made of ‘the stuff of the traditional actions at common law tried by the courts at Westminster in 1789,’ . . . and is brought within the bounds of federal jurisdiction, the responsibility for deciding that suit rests with Article III judges in Article III courts.”) (internal quotation marks and citations omitted)). In addition, under the United States Supreme Court’s decision in *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011), an Article I court must employ *de novo* review to comply with the Constitution, despite the Omnibus Reconciliation Act of 1989, Pub. L. 101-239, sec. 6601(h), 103 Stat. 2106, 2289, amended in 2006, limiting judicial review to an arbitrary and capricious standard. Pet. Mem. at 22 (citing *Bruesewitz* 131 S. Ct. at 1082 (holding that the Vaccine Act preempts “design-defect claims against vaccine manufacturers”)).

Second, Petitioner argued that the Special Master's determination that Petitioner did not meet the requisite burden of proof was arbitrary, capricious, and not in accordance with law. Pet. Mem. at 22. The United States Court of Appeals for the Federal Circuit has held that establishing "a hard and fast deadline of three weeks for the onset of neurological symptoms" has no reasonable basis. *Paluck*, 786 F.3d at 1384. This is, because "[t]here is a wide variety of mitochondrial disorders and those disorders are as yet poorly understood by the medical community." *Id.* In this case, the Special Master's "inflexibly determined that the time frame between vaccination and the onset of staring spells was too short."¹² Pet. Mem. at 24. In reaching this conclusion, the Special Master misconstrued Petitioner's expert, Dr. Kendall's testimony about A.I.'s January 11, 2008 staring spells as the first sign of decompensation. Pet. Mem. at 24. But, as Dr. Kendall testified, the documented decompensation event was A.I.'s multiple collapses on January 22, 2008—11 days after the FluMist vaccine was administered. Pet. Mem. at 26 (citing 7/26/13 TR at 62–64). Moreover, the Special Master erred in relying on EDMONDS to conclude that decompensation caused by a vaccination could not occur within hours of the vaccination. Pet. Mem. at 27. "The meaning of . . . *Paluck*, however, was just the opposite, finding that a clear-cut determination for the time of onset could not be based on such small studies[.]" Pet. Mem. at 27.

Third, Petitioner argued that the Special Master improperly ignored evidence that the "combined stressors of illness plus vaccination explained A.I.'s decompensation." Pet. Mem. at 28. The Special Master's also disregarded the fact that A.I. had significantly recovered from an illness at the time she received the FluMist vaccine. Pet. Mem. at 29. "[I]n fact[,] it was [A.I.'s] lack of symptoms of illness that justified the pediatrician's recommendation to give the vaccination [on January 11, 2008.]" Pet. Mem. at 29. The Special Master also disregarded "Dr. McCandless's concession that the vaccine adds metabolic stress that could be identified as the precipitating factor for decompensation." Pet. Mem. at 29. Instead, Dr. McCandless agreed that 11 days after a triggering event "is consistent with mitochondrial decompensation." Pet. Mem. at 33.

Finally, Petitioner contended that the Special Master imposed an increased burden of proof under Prongs 1 and 2 of *Althen*. In *Paluck*, the United States Court of Appeals for the Federal Circuit "unequivocally affirmed a finding of entitlement based on the identical theory of causation urged by Petitioner[.]" Pet. Mem. at 39. In this case, "the Special Master evaluate[d] each evidentiary item offered by Petitioner without consideration of their cumulative effect in establish[ing] the plausibility and reliability of Petitioner's medical theory." Pet. Mem. at 40. In addition, the Special Master's conclusion that "Flu[M]ist would not cause an actual infection" is unsupported by this record. Pet. Mem. at 42.

¹² The Special Master also misconstrued Dr. Kendall's testimony concluding that, if staring spells occurred on the same day as the FluMist vaccination, A.I.'s subsequent decompensation was more likely caused by her pre-existing infections. Pl. Mem. at 24 (citing 3/17/16 Dec. at 13).

2. The Government's Response.

The Government responded that, in *Paluck*, the Government neither agreed nor conceded that the causation theory propounded was reliable under Prong 1 of *Althen*. Gov't Mem. at 9–10. Instead, the Government in *Paluck* merely accepted the United States Court of Federal Claims' findings solely for purposes of appeal. Gov't Mem. at 10. In any event, "the facts and circumstances of this case are distinguishable from [*Paluck*.] The fact that the [Petitioner] cites to the same articles as relied on by the Petitioner in *Paluck* does not signify that a proven theory of causation in one case . . . will apply to another." Gov't Mem. at 10. Even if they weren't, "[f]act-based determinations of causation[,] in cases under the Vaccine Act[,] are not binding precedent in other cases under the Act." Gov't Mem. at 10 (citing *Hanlon v. Sec'y of Health & Human Servs*, 40 Fed. Cl. 625, 630 (1998) ("Special [M]asters are neither bound by their own decisions nor by cases from the [United States] Court of Federal Claims, except, of course, in the same case on remand."), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999)).

Next, the Government turned to the Special Master's determination that Dr. Kendall's theory was speculative. Gov't Mem. at 11. Both Dr. Kendall and Dr. McCandless testified that "there have been no studies attributing acute metabolic decompensation in a child with Leigh [D]isease to the influenza vaccine." Gov't Mem. at 12 (citing 3/17/16 Dec. at 11). Nor could Dr. Kendall support a theory that the additional stress of the FluMist vaccine contributed to A.I.'s decompensation. Gov't Mem. at 12. In fact, when questioned, Dr. Kendall was "neither able to quantify how much oxidative stress was produced by either A.I.'s illness or her vaccination, nor could she determine the amount that was produced by the two factors combined." Gov't Mem. at 13 (citing 7/26/13 TR at 98–100). Dr. Kendall also was unable to state how much oxidative stress would be required to trigger decompensation in a Leigh Disease patient such as A.I. Gov't Mem. at 13 (citing 7/26/13 TR at 99–100). And, with respect to Dr. Kendall's reliance on FluMist's marketing package information, the Special Master correctly determined this evidence as unreliable, because Dr. Kendall agreed that FluMist was not contraindicated for patients with Leigh Disease. Gov't Mem. at 13–14. With respect to the articles Dr. Kendall cited, the Special Master correctly determined they did not support her theory of causation. Gov't Mem. at 14. Likewise, the facts in this case are distinguishable from those cited in *POLING* that described "one child with a mitochondrial disease, not Leigh [D]isease, who experienced an *autistic regression* after vaccination[.]" Gov't Mem. at 14 (emphasis in original). Specifically, the facts in this case also are distinguishable from *SHOFFNER* in that "none of the children had Leigh Disease [and] none developed metabolic decompensation [since] the purpose of the study was to study fever, not vaccines." Gov't Mem. at 14. With respect to Dr. Kendall's citation to articles studying the wild flu virus, the Special Master properly discerned they were not applicable, because the attenuated virus would cause an immune response without an infection; the wild flu virus, however, would cause an infection. Gov't Mem. at 15 (citing 3/17/16 Dec. at 25–26).

As to Petitioner's argument that the Special Master's determination is inconsistent with *Paluck*, the Special Master specifically did not attribute a "hard and fast deadline" to the onset of the first symptom but rather determined that Dr. Kendall's testimony failed to cite to "any medical literature specifically addressing the timing of mitochondrial decompensation[.]" Gov't Mem. at 17 (quoting 3/17/16 Dec. at 13). Although Dr. Kendall relied on several articles that

had been referenced in *Paluck*, none of Dr. Kendall's articles addressed timing as required by *Althen* Prong 3 nor decompensation after FluMist vaccination. Gov't Mem. at 17.

Finally, Petitioner's argument regarding the constitutionality of the Vaccine Act is meritless. Gov't Mem. at 18–19. “[C]onsistent with the requirement that Article III courts have ‘supervisory authority over the process,’ the decision of the Special Master can be reviewed by both the [United States Court of Appeals for] the Federal Circuit and the [United States] Supreme Court.” Gov't Mem. at 19 (quoting *R.K. v. Sec'y of Health & Human Servs.*, 125 Fed. Cl. 57, 71 (2011)).

In sum, the Special Master carefully reviewed and discussed the medical literature cited and opinions provided by both experts and determined that Petitioner failed to meet the requisite burden of proof. Gov't Mem. at 16.

3. The Court's Resolution.

With respect to the Special Master's determination that Dr. Kendall's expert opinion was unpersuasive, it is well established that “[f]inders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented . . . and, if appropriate, as to the credibility of the persons presenting that evidence.” *See Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1326 (Fed. Cir. 2010); *see also Malik*, 822 F.3d at 1381 (“[A] [S]pecial [M]aster's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories, and . . . the [S]pecial [M]aster's credibility findings are virtually unchallengeable on appeal.”) (internal quotation marks omitted). The March 17, 2016 Decision shows that the Special Master thoroughly reviewed the record, expert testimony, and the articles each expert cited, and determined that Dr. McCandless was more credible than Dr. Kendall, because Dr. Kendall “effectively admitted that certain aspects of her causation opinion were speculative.” 3/17/16 Dec. at 12. Nevertheless, the Special Master did not ignore evidence from Dr. Kendall that A.I.'s illness combined with the vaccination triggered her decompensation. Instead, citing testimony from Dr. Kendall and Dr. McCandless, the Special Master noted that both “experts agree that the significance of A.I.'s January 11 illness, or any of her prior illnesses, is effectively unknowable.” 3/17/16 Dec. at 16. Accordingly, the Special Master properly “considered the relevant evidence of record,” *Hines*, 940 F.2d at 1524, when he determined that Dr. Kendall's opinion did not establish a “medical theory causally connecting the vaccination and the injury.” *Althens*, 418 F.3d at 1278.

Petitioner insisted, however, that, because the United States Court of Appeals for the Federal Circuit “accepted” the validity of a petitioner's causation theory in *Paluck*, the Special Master in this case also was obligated to accept the validity of Petitioner's causation theory. Pet. Mem. at 39–40. *Paluck* does not stand for this proposition. Although Petitioner relied on two studies discussed in *Paluck*—POLING and SHOFFNER—citing to these studies does not meet the burden of causation. In fact, the Special Master properly observed, POLING and SHOFFNER were not comparable to A.I.'s medical situation since they discussed *autistic regression* after vaccination, not Leigh Disease nor respiratory failure after vaccination. *See* POLING, ECF No. 26-8 at 1–2; *see also* SHOFFNER, ECF No. 26-9 at 1–4.

Petitioner also insisted that the Special Master increased Petitioner's burden by evaluating each evidentiary item, without considering the cumulative effect. Pet. Mem. at 42. But, the Special Master stated that under Prong 1 of *Althen*, in addition to the fact that the marketing evidence was not persuasive,

Petitioner's reliance on the Poling and Shoffner articles, among other articles, and on the *Paluck* opinion, was also shown to be without merit. . . . Petitioner additionally sought to establish that the flu virus is capable of causing cell death, but failed to demonstrate that the type of *attenuated* viral strain contained in the FluMist vaccine at issue would have the same effect on the body as an infection from a *wild* flu virus.

3/17/16 Dec. at 30 (emphasis in original). As such, the cumulative effect of the evidence was that "Petitioner was unable to explain persuasively how the FluMist vaccine might have caused or contributed to the type of decompensation that A.I. sustained." 3/17/16 Dec. at 30.

Petitioner also contended that the Special Master improperly increased Petitioner's burden, because he concluded that the FluMist vaccine would not cause an actual infection without support in the record. But, after reviewing Dr. Kendall's cited articles on the wild influenza virus, the Special Master determined that these articles were irrelevant, because they did not discuss "the type of *attenuated strain* contained in a FluMist vaccine." 3/17/16 Dec. at 26 (emphasis in original). In light of this finding, the Special Master concluded that "there is no evidence that A.I.'s FluMist vaccine created an actual infection, as opposed to merely an immune response, following her vaccination." 3/17/16 Dec. at 26. Therefore, the Special Master properly concluded that Prong 2 of *Althen* was not established, because Petitioner did not to show a logical sequence of cause and effect. 3/17/16 Dec. at 31.

As to the temporal element of causation, Petitioner is correct that the United States Court of Appeals for the Federal Circuit has held that "[g]iven the heterogeneity of mitochondrial defects and the paucity of scientific literature discussing the impact that vaccination has on persons suffering from such defects, the special master had no reasonable basis for setting a hard and fast deadline of three weeks for the onset of neurological symptoms." *Paluck*, 786 F.3d at 1384. But, the Special Master did not set "a hard and fast deadline" in this case. Instead, relying on EDMONDS, the Special Master decided that the onset of A.I.'s staring spells hours after the FluMist vaccination "would likely be *too soon* to be related to the vaccination." 3/17/16 Dec. at 14 (emphasis in original). The Special Master reasoned that, if A.I.'s collapse on January 22, 2008 was the first symptom of decompensation, he "would still have to reject the Petitioner's causation claim," because Dr. Kendall cited no medical literature to substantiate her testimony regarding the temporal relationship between A.I.'s vaccination and decompensation, *i.e.*, *Althen* Prong 3. 3/17/16 Dec. at 14 n.8, 15.

Finally, the Vaccine Act does not deny a Petitioner access to an Article III court. In fact, Petitioners may appeal this decision to the United States Court of Appeals for the Federal Circuit. See 42 U.S.C. § 300aa-12(f) ("[A]ny petitioner aggrieved by the findings or conclusions of the [United States Court of Federal Claims] may obtain review of the judgment of the court in the United States Court of Appeals for the Federal Circuit[.]"). And, if unsatisfied, Petitioner may file a petition for certiorari to the United States Supreme Court. In addition, Petitioner has

misread *Stern*'s holding that Article I bankruptcy courts do not have jurisdiction over common law claims between *private* parties. *See Stern*, 131 S. Ct. at 2614–15 (holding that the relevant claim was under state common law between two private parties, so that Congress had “nothing to do with it”). The claims in this case, are alleged against the Government, not a private party. In addition, the United States Court of Appeals for the Federal Circuit directly addressed the constitutionality of the Vaccine Act and concluded that the United States Supreme Court's “decision in *Stern* does not apply in these circumstances, and because the [Supreme] Court's decision in *Bruesewitz* has no bearing on the applicable standard of review, we continue to review the [S]pecial [M]aster's findings of fact under the deferential arbitrary and capricious standard.” *Milik*, 822 F.3d at 1378–79. Moreover, *Stern* recently has been distinguished in *Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1944 (2015) where the United States Supreme Court held that, “allowing Article I adjudicators to decide claims submitted to them by consent does not offend the separation of powers so long as Article III courts retain supervisory authority over the process.”

For these reasons, the court has determined that the Special Master's March 17, 2016 Decision denying entitlement was not “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 42 U.S.C. § 300aa-12(e)(2); *see also Hines*, 940 F.2d at 1528, (requiring the Special Master to consider “the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis for the decision”).

IV. CONCLUSION.

For the reasons discussed, the court denies Petitioner's April 18, 2016 Motion For Review. The Clerk of the Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Susan G. Braden
SUSAN G. BRADEN
Judge